When A 510(k) or PMA Goes Off Track: What Are The Appeal Options?

AMDM Meeting

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FDA as Gatekeeper

- Most medical devices require 510(k) clearance or premarket approval prior to marketing
- Obtaining clearance or approval is more challenging today
  - Device technology is more complex
  - Regulatory requirements are more demanding

Illustrative Points of Conflict

- 510(k)
  - Refusal to file
  - Request for additional information –
    - Rejecting predicates
    - Requiring additional data, clinical or otherwise
  - Not substantially equivalent
    - Lack of predicate
    - Lack of adequate performance data
  - Rescission?

Illustrative Points of Conflict

- PMA
  - Refusal to file
  - Major/minor deficiency letter
  - “Not approvable” or denial
- Request for Designation (RFD)
  - Refusal to file
  - Lead center determination

Try to Avoid An Appeal !!

- Process is slow, inefficient, and uncertain
- Start by trying to avoid one
  - Arguing with the primary review team probably won't change their minds
  - Try to offer new information or data as the basis for a proposed alternative
  - Won't always work, but it is worth a try

"Negotiating" with FDA

- Key Dynamics
  - FDA holds most of the power
  - FDA personnel are busy and any one matter is not necessarily a priority
  - FDA tends to operate by group decision, so there is not a point person with delegated authority to make real time decisions
- Result: Negotiations are slow and iterative
- These dynamics can apply on appeal as well

Appeal Guidance

- MEDICAL DEVICE APPEALS AND COMPLAINTS: Guidance On Dispute Resolution (1998)
- Resolving Scientific Disputes Concerning The Regulation Of Medical Devices, A Guide To Use Of The Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA (2001)

Supervisory Review (21 CFR 10.75)

- Applicant submits written request to supervisor (and appeals can continue up the supervisory chain)
  - E.g. An NSE decision by Division could be appealed to the Director of OIVD
- Based on the official administrative file – no new information
  - If new information provided, matter will be returned to lower level for reevaluation

Supervisory Review (21 CFR 10.75)

- CDRH personnel and applicant – not public
- Under regulations, appeal involves consultation between supervisor and employee, or supervisor's review of the file

Supervisory Review (21 CFR 10.75)

- Process is informal
  - Typically, applicant submits written statement of the dispute
  - Advisable to request a meeting; usually granted
- Potential outcomes include: favorable decision, partially favorable decision, denial or a brokered "settlement"

Supervisory Review (21 CFR 10.75)

- Generally the quickest and least expensive appeal option
- Not ideal
  - Upper management is busy, so appeals tend to languish
    - No mandatory time requirements
  - Upper management is presumptively reluctant to overrule primary review team

Supervisory Review (21 CFR 10.75)

- If the dispute is scientific, applicant may request panel review
  - Medical Devices Dispute Resolution Panel
- Rarely used

Defining Issues on Appeal

- Keep it simple – focus on defined errors that justify reversal
  - The more complex the dispute, the greater the likelihood that upper management will defer
  - Don't present the *Iliad* and the *Odyssey*, focus on key procedural history
  - Don't cast aspersions – just present facts

Legal/Regulatory Issue?

- May be able to characterize some or all of the dispute in legal /regulatory terms
  - Especially if precedents are being disregarded
- Could present issue to Office of Chief Counsel for opinion
  - Issue must be “ripe” and not scientific

Other Appeal Procedures

- Citizen's Petition (21 C.F.R. 10.30)
- Petition for Administrative Reconsideration (21 C.F.R. 10.33)
- 21 CFR Part 12 - Formal Evidentiary Public Hearing
- 21 CFR Part 13 - Public Hearing Before A Board of Inquiry

Other Appeal Procedures

- 21 CFR Part 14 - Public Hearing Before A Public Advisory Committee
- 21 CFR Part 16 - Regulatory Hearing Before the Food and Drug Administration

Reform Is Needed

- Many formal procedural options offer elaborate "due process" – but are not commercially viable
  - Hardly ever used
  - Require deep pockets and plenty of time

Reform Is Needed

- Informal supervisory appeals are almost always the only realistic choice
- Shortcomings
  - Must be fit into upper management's busy workload
    - No mandatory timelines
    - No performance metrics
  - Direct supervisory management will presumptively side with the review team (although it is possible to gain reversals)

Reform Proposal – Office of Appeals

- Office of Appeals for Premarket Submissions
  - In the CDRH Director's Office
  - Reporting to the CDRH Ombudsman)
- With dedicated staff
  - Multidisciplinary scientific / medical expertise, and varied premarket review experience
  - Access to dedicated OCC counsel when needed
- Operating under a written procedure with established milestones and timelines

Office of Appeals – Advantages

- Would regularize the appeals process
- Would develop an experienced team processing appeals more efficiently and consistently
  - Could develop a database with information about dispute and resolution patterns
  - May develop data-based insight into the performance of review divisions
- Creates a single office to hold accountable with metrics for timely and fair appeals